REMARKS/ARGUMENTS

Prior to making remarks and arguments in favor of the patentability of the present application's pending claims, Applicants call to the attention of the Examiner, related co-pending applications 10/857,177 (Attorney Docket No. 021872-002000US) and 10/974,008 (Attorney Docket No. 021872-002010US). These cases are presently in active prosecution before different Examiners. Applicants assume the Examiner has access to the prosecution files of these cases but will provide copies of the relevant prosecution papers if requested.

Claims 19-34 were examined, with claims 1-18 having been previously withdrawn pursuant to a restriction requirement and subsequently cancelled. Reexamination and reconsideration of the claims, as amended above, are respectfully requested.

Claim Rejections - 35 U.S.C. §102

Independent claim 19 was rejected under 35 U.S.C. §102(e) as allegedly being anticipated by US Patent No. 6,913,614 to Marino et al. (hereinafter Marino). The rejections are traversed in part and overcome in part as follows.

Independent claim 19, as amended, recites:

An expansible device for use in a body lumen or tract, the device comprising:

a tubular member having a proximal end and a distal end;

a first expansible member disposed on the distal end of the tubular member, the first expansible member having a contracted configuration and an expanded configuration, wherein the first expansible member comprises a single wire that can be shifted between a straightened ~~an elongate~~ contracted configuration and a helical expanded configuration;

a first deformable membrane at least partially disposed over the first expansible member in the expanded configuration;

a second expansible member disposed proximal to the first expansible member and on the [[a]] distal end of the tubular member, the second expansible member having a contracted configuration and an expanded configuration.

wherein the first deformable membrane has a spherical shape when the first expansible member is in the expanded configuration and the second expansible member has a cylindrical shape in the expanded configuration.

Marino fails to disclose each and every element of claim 19. In particular, Marino is missing an expansible member comprising a wire having a helical expanded configuration, the term helical being consistent with the common definition of a "helix". As seen in Fig. 1 of Marino, each of the six arms 26 of distal fixation devices 22, 24 projects radially outward from center section 20 when the distal fixture device is in an expanded state. No one skilled in the art would consider the radially outwardly projecting arms of Marino as forming a "helix". Thus, Marino fails to disclose the first expansible member as required by claim 19.

Nevertheless, to further clarify and distinguish the claimed subject matter, claim 19 has been amended to recite, "wherein the first expansible member comprises a single wire that can be shifted between a straightened ~~an elongate~~ contracted configuration and a helical expanded configuration". As mentioned above, Marino uses multiple, radially projecting arms 26 to deploy its fixation devices and would fail to meet the limitation of a "single wire".

Without conceding to the correctness of the present rejection or any others, claim 19 has also been amended to further recite the limitations of claims 20 and 27. Claim 19 as amended reads, "the first deformable membrane has a spherical shape when the first expansible member is in the expanded configuration and the second expansible member has a cylindrical shape in the expanded configuration". The expanded fixation devices 22 and 24 of Marino are both flat and umbrella shaped and thus fail to meet the geometries (one spherical and the other cylindrical) required by claim 19.

For at least the reasons above, Applicants submit that independent claim 19 is allowable over Marino.

Independent claim 19 and claims 20, 22, 24 and 25 which depend thereon were also rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US Patent No. 5,831,003 to Latson et al. (hereinafter Latson). The rejections are overcome as follows.

As discussed above, claim 19 as amended requires that the first deformable membrane have a spherical shape and the second expansible member have a cylindrical shape in their expanded configurations. Latson fails to disclose structures which have these geometries. Latson shows expansible sacs 5, 6 which are interconnected via sac joining connector 7, all of which are components of occlusion bag 4. Sacs 5 and 6 assume the same disc shape when expanded (Figs. 3-5).

In contrast, the present invention as claimed requires two distinct expansible elements, each of which assumes a different shape. The first deformable membrane (disposed over the first expansible member) assumes a spherical shape. The second expansible member assumes a cylindrical shape. This can confer several advantages. For example, by having distinct expansible elements, the expansible elements may be deployed sequentially or simultaneously ([0079]). Additionally, the expansible members may each be expanded by differing mechanisms. For example, the first deformable membrane may be expanded by a wire coil while the second expansible member may be air inflatable ([0078]). In Latson, both sac 5 and 6 are expanded by the same wire support frame 9 (Col. 4, Ln. 48-65).

The differing geometries of the first deformable membrane and second expansible member of the present invention are also important, particularly in facilitating hemostasis ([0077]). For example, a puncture through a blood vessel may be compressed between the first deformable membrane and second expansible member. The first deformable membrane is spherical and provides hemostasis at the puncture on the side of the inner vessel wall facing the vessel lumen. The second expansible member provides hemostatis at the end of the puncture on the side of the outer vessel wall. Also, since the second member is cylindrical and is located in the tissue track once the device is anchored, it can also provide hemostasis means for the tissue track, see Fig. 11E and paragraph [0079]. The expansible structures are disclosed by Latson are designed to properly cover septal wall defects and are thus both flat and disc shaped. They would fail to confer the advantages of the present invention discussed above.

Because Latson fails to disclose each and every element of independent claim 19 as amended, Applicants submit that claim 19 and the claims dependent thereon are allowable over Latson.

Independent claim 19 and claims 26 to 28 which depend thereon were still further rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US Patent Publication No. 2002/0111647 to Khairkhahan et al. (hereinafter Khairkhahan). The rejections are traversed in part and overcome in part as follows.

Khairkhahan fails to disclose each and every element of claim 19. Like Marino, Khairkhahan fails to disclose an expansible member which comprising a wire with a helical expanded configuration, the term helical being consistent with the common definition of a "helix". In Khairkhahan, the distal portion 190 of the occlusion device 10, which the Examiner has construed as the "expanded configuration", is comprised of spokes 218 with an apex 220. In the configuration shown, the spokes 218 each project radially outwards, as seen in Figs. 7 to 7B and as described by paragraphs [0044] and [0045]. No one skilled in the art would consider the radially outwardly projecting spokes of Khairkhahan as forming a "helix". Therefore, Khairkhahan fails to disclose the "first expansible member" as required by claim 19 and thus fails to anticipate claim 19 and the claims dependent thereon.

Additionally, claim 19 has been amended to recite a "single wire" as discussed above. Khairkhahan use multiple, radially projecting arms or spokes to deploy its occlusion device.

Also as discussed above, claim 19 has been amended to also recite the geometries of the first deformable membrane and the second expansible member in expanded configurations. The expanded first deformable membrane is spherical while the expanded second expansible member is cylindrical. Occluding member 11 and stabilizer 194 of Khairkhahan fail to meet the required geometries.

For at least the reasons above, Applicants submit that independent claim 19 and the claims dependent thereon are allowable over Khairkhahan.

Claim Rejections - 35 U.S.C. §103(a)

Claims 19, 20, 21, 29, 30 and 32-34 were rejected as being obvious over U.S. Patent No. 6,071,300 to Brenneman et al. (hereinafter Brenneman) in view of U.S. Patent No. 5,061,274 to Kensey et al (hereinafter Kensey). The rejections are traversed in part and overcome in part as follows.

Neither Brenneman nor Kensey alone or in combination disclose each and every element of independent claim 19 nor of independent claim 29. Of note, independent claim 19 reads, "the first expansible member comprises **a wire** that can be shifted between **an elongate contracted configuration** and **a helical expanded configuration**"; independent claim 29 recites "causing ~~deploying~~ a straight ~~helical~~ wire within the first expansible member to assume a helical configuration such that it expands ~~expand~~ the expansible member to an expanded configuration comprising a spherical shape" and "deploying the second expansible member to an expanded configuration comprising a cylindrical shape."

The device of Brenneman comprises an inflatable intravascular locating balloon 50 and a compression balloon 42, respectively coupled to a first axial lumen 36 and a second axial lumen 38 having an inflation orifice 40 (Col. 5, Ln. 38-55). While the balloons 42 and 50 are expansible and balloon 42 is proximal to balloon 50, both are expanded by inflation and do not comprise a **wire,** much less a **wire** that can be shifted between **an elongate contracted configuration** and **a helical expanded configuration**. Therefore, Brenneman does not disclose the "first expansible member" as required by claim 19 nor the step associated with the "first expansible member" as required by claim 29.

The Examiner had argued that distal end 82 of guidewire 78 is the "wire" of the "first expansible element". Such argument is misplaced. Claim 29 had required, "deploying a helical wire within the first expansible member to expand the expansible member to an expanded configuration comprising a spherical shape". As seen in Figures 1A-1C and 4A-4F, the distal end 82 of guidewire 78 in no way expands balloon 50 as required by claim 29.

Kensey refers to instruments and methods for sealing small incisions or punctures. It fails to provide the missing elements from Brenneman as it does not even remotely disclose a

"first expansible member" comprising **a wire** as required by claim 19 nor "a helical wire within the first expansible member" as required by claim 29.

Nevertheless, to further clarify and distinguish the claimed subject matter, claim 19 has been amended as previously discussed and claim 29 has been amended to recite, "causing ~~deploying~~ a straight ~~helical~~ wire within the first expansible member to assume a helical configuration such that it expands ~~expand~~ the expansible member to an expanded configuration comprising a spherical shape". Support for the amendments to claim 29 can be found in paragraph [0055]-[0057] and [0078]. No new matter has been added.

As neither Brenneman nor Kensey alone or in combination disclose each and every element of independent claim 19 and of independent claim 29, *prima facie* obviousness cannot be established. Additionally, claim 19 and 29 have each been amended for clarity as noted above. As all claims depend from either claim 19 or 29, Applicants submit that all claims are allowable over Brenneman in view of Kensey.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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